

## REMARKS

### Claim Status

Claims 1, 2, 3, 5, 10, 12, 14, 18 and 21 are pending in the application. Claims 4, 6-9, 11, 13, 15-17, 19-20, 22 are withdrawn from consideration. By this amendment, claims 1, 3-5, 13, 15 are amended and claims 2, 10 and 14 are cancelled. In particular, claim 14 is cancelled to address the statutory double patenting rejection.

It is respectfully submitted that the amendments to the claims do not introduce any new subject matter into the application.

### Priority

The Office Action asserts that the prior-filed application U.S. Provisional Application No. 60/435,834, does not provide adequate support or enablement as per 35 U.S.C. § 112, first paragraph for claim 14. This issue is moot in view of Applicants' cancellation of claim 14 with this amendment.

### Rejection under 35 U.S.C. § 112, second paragraph

Claims 10 and 14 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This ground of rejection is now moot in view of Applicants' cancellation of claims 10 and 14.

### Claims rejection under 35 USC § 103

Claims 1, 2, 3, 5, 10, 12, 14, 18 and 21 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Cairns et al. (J.Chem.Soc., Perkins Trans. 1(14), 1558-64, 1976)) in view of Ahlem et al. (WO00/56757). The Applicant respectfully disagrees. Nevertheless in order to advance the case to allowance, the pending claims have been amended. In light of the present amendments, the Applicants request reconsideration and withdrawal of the rejection.

Cairns et al. discloses 16-alpha-substituted 17-alpha-methylpregnanes and their glucocorticoid activity. This document is completely silent on a compound as presently claimed

and its surprising effect as an antimigratory and an anticancer agent. There is no teaching in Cairns et al. which would have prompted the skilled man in the art to modify the compounds of Ahlem et al. to arrive at the present invention.

Ahlem et al. only describes a generic markush of formula 1 which encompasses an infinite number of compounds. None of the particular embodiments or preferred embodiments of said disclosure teaches or suggests compounds as presently claimed with the specific selection of substituents listed in claim 1. For example, the Examiner relies upon Ahlem for teaching "R3 is a substituted aryl group, including p-dimethoxybenzene" (Office Action, page 9, line 4) which is a required element for claim 1 as amended and for all pending claims under examination. However, Ahlem, et al. merely state that any of R<sub>1</sub>, R<sub>2</sub>, R<sub>3</sub>, R<sub>4</sub>, R<sub>5</sub>, R<sub>6</sub>, or R<sub>10</sub> in Formula 1 (page 5) can be selected from a laundry list of diverse elements which may include "an optionally substituted aryl moiety" (Ahlem, et al., page 5, line 17-18). The Examiner then refers to p. 15, lines 15-25 of Ahlem, et al. for a definition of substituted aryl group (Office Action, page 9, lines 8). Here again there is a long list of possible substituents, including "-O-A8-". For "A8" there is again a comprehensive list of possible substituents, including C<sub>1-8</sub>alkyl. As Ahlem, et al. also mentions that "typical substitutions for these organic groups include 1, 2, 3, 4 or more, usually 1 or 2..." (page 15, lines 19-20), the Examiner asserts that Ahlem, et al. teach p-dimethoxybenzene (Office Action, page 9, line 4). However, this substituent is never specifically taught by Ahlem, et al. but is only pieced together from disparate parts of a lengthy disclosure. Accordingly, there is no guidance in Ahlem, et al. to arrive at the compounds of claim 1 as now claimed.

There is no teaching in Ahlem et al. that would have motivated or directed the skilled man in the art to explore modifications of the compounds of Cairns, to arrive at the presently claimed anticancer compounds.

The specific selection of substituent allows the present inventors to synthesize antimigratory and anticancer agent. The present inventors have shown that the compounds falling under the present claims present surprising anticancer and antimigratory activity as it can be seen from the results listed in Tables E and F of the present application.

Thus, one of skill in the art would not be motivated to combine the teachings of these two documents, as has been done in the Office Action. For at least these reasons, a *prima facie* case

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of obviousness has not been made and the Applicants respectfully request withdrawal of the rejection.

#### **Double patenting**

Claim 14 is provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 21 of copending Application No. 10/582,121.

This rejection is addressed by cancellation of claim 14. Accordingly, this rejection may be withdrawn.

Claims 1, 2, 3, 5, 10, 12, 18, and 21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4, 5, 6, 8, 10, 13, and 37 of copending Application No. 10/582,121. A Notice of Allowability has been issued for US Application No. 10/582,121. Applicants respectfully request that the double patenting rejection be held in abeyance until allowable subject matter is indicated in the present application.

#### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

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**CONCLUSION**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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